REMOVABLE TIP FOR LASER DEVICE WITH SAFETY INTERLOCK

This application is a continuation of U.S. Patent Application Serial No. 10/091,957, filed on March 5, 2002, which is a continuation of U.S. Patent Application Serial No. 09/457,953, filed on December 9, 1999, which is a divisional of U.S. Patent Application Serial No. 08/955,789, filed on November 19, 1999 and now issued as U.S. Patent No. 6,315,772, which is a continuation-in-part of of U.S. Patent Application Serial No. 08/792,335, filed January 31, 1997, incorporated herein by reference, now abandoned, which is a continuation-in-part of U.S. Patent Application Serial No. 08/126,241 filed on Setember 24, 1993, now issued as U.S. Patent No. 5,643,252.

FIELD OF THE INVENTION

This invention relates to medical devices, and in particular to laser devices for altering skin permeability.

SUMMARY OF THE INVENTION

In one aspect of the invention, an applicator for use with a laser device housing comprises an applicator body mountable for moving in the housing when at least a minimum amount of pressure is applied to the applicator by contact with a patient's skin to actuate a mechanism in the housing for operation of the laser device, and an applicator distal end affixed to the body and positionable substantially in a focal plane of the laser device by motion of the body upon application of at least the minimum amount of pressure.

In another aspect of the invention, a method for forming an applicator for use with a laser device housing comprises selecting an applicator body mountable for moving in the housing when at least a minimum amount of pressure is applied to the applicator by contact with a patient's skin to actuate a mechanism in the housing for operation of the laser device, and affixing an applicator distal end to the body to be positionable substantially in a focal plane of the laser device by motion of the body upon application of at least the minimum amount of pressure.

DETAILED DESCRIPTION

The present invention employs a laser to perforate or alter the skin of a patient so as to remove fluids, gases or other biomolecules or to administer anesthetics or other pharmaceuticals. Perforation or alteration is produced by irradiating the surface of the target tissue with a pulse or pulses of electromagnetic energy from a laser. Prior to treatment, the care giver properly selects the wavelength, energy fluence (energy of the pulse divided by the area irradiated), pulse temporal width and irradiation spot size so as to precisely perforate or alter the target tissue to a select depth and eliminate undesired damage to healthy proximal tissue.

According to one embodiment of the present invention, a laser emits a pulsed laser beam, focused to a small spot for the purpose of perforating or altering the target tissue. By adjusting the output of the laser, the laser operator can control the depth, width and length of the perforation or alteration as needed.

In another embodiment continuous-wave or diode lasers may be used to duplicate the effect of a pulsed laser beam. These lasers are modulated by gating their output, or, in the case of a diode laser, by fluctuating the laser excitation current in a diode laser. The overall effect is to achieve brief irradiation, or a series of brief irradiations, that produce the same tissue permeating effect as a pulsed laser. The term "modulated laser" is used herein to indicate this duplication of a pulsed laser beam.

The term, "perforation" is used herein to indicate the ablation of the stratum corneum to reduce or eliminate its barrier function. The term, "alteration" of the stratum corneum is used herein to indicate a change in the stratum corneum which reduces or eliminates the barrier function of the stratum corneum and increases permeability without ablating, or by merely partially ablating, the stratum corneum itself. A pulse or pulses of infrared laser radiation at a subablative energy of, e.g., 60 mJ (using a TRANSMEDICA™ International, Inc. ("TRANSMEDICA™") Er:YAG laser with a beam of radiant energy with a wavelength of 2.94 microns, a 200 μs (microsecond) pulse, and a 2 mm spot size) will alter the stratum corneum. The technique may be used for transdermal drug delivery or for obtaining samples, fluids, gases or other biomolecules, from the body. Different wavelengths of laser radiation and energy levels less than or greater than 60 mJ may also produce the enhanced permeability effects without ablating the skin.

The mechanism for this alteration of the stratum corneum is not certain. It may involve changes in lipid or protein nature or function or be due to desiccation of the skin or mechanical

alterations secondary to propagating pressure waves or cavitation bubbles. The pathway that topically applied drugs take through the stratum corneum is generally thought to be through cells and/or around them, as well as through hair follicles. The impermeability of skin to topically applied drugs is dependent on tight cell to cell junctions, as well as the biomolecular makeup of the cell membranes and the intercellular milieu. Any changes to either the molecules that make up the cell membranes or intercellular milieu, or changes to the mechanical structural integrity of the stratum corneum and/or hair follicles can result in reduced barrier function. It is believed that irradiation of the skin with radiant energy produced by the Er:YAG laser causes measurable changes in the thermal properties, as evidenced by changes in the Differential Scanning Calorimeter (DSC) spectra as well as the Fourier Transform Infrared (FTIR) spectra of the stratum corneum. Changes in DSC and FTIR spectra occur as a consequence of changes in molecules or macromolecular structure, or the environment around these molecules or structures. Without wishing to be bound to any particular theory, we can tentatively attribute these observations to changes in lipids, water and protein molecules in the stratum corneum caused by irradiation of molecules with electromagnetic radiation, both by directly changing molecules as well as by the production of heat and pressure waves which can also change molecules.

Both perforation and alteration change the permeability parameters of the skin in a manner which allows for increased passage of pharmaceuticals, as well as fluids, gases or other biomolecules, across the stratum corneum.

Accordingly, one embodiment of the present invention provides a means for perforating or altering the stratum corneum of a patient in a manner that does not result in bleeding. For example, the perforation or alteration created at the target tissue is accomplished by applying a laser beam that penetrates through the stratum corneum layer or both the stratum corneum layer and the epidermis, thereby reducing or eliminating the barrier function of the stratum corneum. This procedure allows the administration of anesthetics or other pharmaceuticals, as well as the removal of fluids, gases or other biomolecules, through the skin. Moreover, this procedure allows drugs to be administered continually on an outpatient basis over long periods of time. The speed and/or efficiency of drug delivery is thereby enhanced for drugs which were either slow or unable to penetrate skin.

In another embodiment of this invention, pressure waves, plasma, and cavitation bubbles are created in or above the stratum corneum to increase the permeation of the compounds (e.g., pharmaceuticals) or fluid, gas or other biomolecule removal. This method may simply overcome the barrier function of intact stratum corneum without significant alteration or may be used to

increase permeation or collection in ablated or altered stratum corneum. As described herein, pressure waves, plasma, and cavitation bubbles are produced by irradiating the surface of the target tissue, or material on the target tissue, with a pulse or pulses of electromagnetic energy from a laser. Prior to treatment, the care giver properly selects the wavelength, energy fluence (energy of the pulse divided by the area irradiated), pulse temporal width and irradiation spot size to create the pressure waves, plasma, or cavitation bubbles while limiting undesired damage to healthy proximal tissue.

A further embodiment of this invention provides an alternative means for administering drugs that would otherwise be required to be taken through other means, such as orally or injected, thereby increasing patient compliance and decreasing patient discomfort.

An additional embodiment of this invention allows the taking of measurements of various fluid constituents, such as glucose, or to conduct measurements of gases.

This invention avoids the use of sharps. The absence of a contaminated sharp will eliminate the risk of accidental injury and its attendant risks to health care workers, patients, and others that may come into contact with the sharp. The absence of a sharp in turn obviates the need for disposal of biologically hazardous waste. Thus, the present invention provides an ecologically sound method for administering anesthetics or other pharmaceuticals, as well as removing fluids, gases or other biomolecules.

In another embodiment a typical laser is modified to include a container unit. Such a container unit can be added to: (1) increase the efficiency in the collection of fluids, gases or other biomolecules; (2) reduce the noise created when the laser beam perforates the patient's tissue; and (3) collect the ablated tissue. The optional container unit is alternatively evacuated to expedite the collection of the released materials such as the fluids, gases or other biomolecules. The container can also be used to collect only ablated tissue. The noise created from the laser beam's interaction with the patient's skin may cause the patient anxiety. The optional container unit reduces the noise intensity and therefore alleviates the patient's anxiety and stress. The container unit also minimizes the risk of cross-contamination and guarantees the sterility of the collected sample. The placement of the container unit in the use of this invention is unique in that it covers the tissue being irradiated, at the time of irradiation by the laser beam, and is therefore able to collect the fluid, gas or other biomolecule samples and/or ablated tissue as the perforation or alteration occurs. The container unit may also be modified for the purpose of containing materials, such as drugs, which may be applied before, simultaneously or shortly after irradiation.

A typical laser used for this invention requires no special skills to use. It can be small, light-weight and can be used with regular or rechargeable batteries. The greater the laser's portability and ease of use, the greater the utility of this invention in a variety of settings, such as a hospital room, clinic, or home.

Safety features can be incorporated into the laser that require that no special safety eyewear be worn by the operator of the laser, the patient, or anyone else in the vicinity of the laser when it is being used.